

PD4 Exh 10

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION

MDL No. 2804

Case No. 17-MD-2804

This document relates to:

Judge Dan Aaron Polster

Track One Cases:

**DEFENDANTS WALGREEN CO. AND WALGREEN EASTERN CO.'S
SECOND SUPPLEMENTAL RESPONSES TO PLAINTIFFS'
"(FIRST) COMBINED DISCOVERY REQUESTS"**

Defendants Walgreen Co. and Walgreen Eastern Co. ("Walgreens") hereby respond to "Plaintiffs' (First) Combined Discovery Requests to the National Retail Pharmacies Defendants" in accordance with the Federal Rules of Civil Procedure 26 and 34, the Local Rules of the Northern District of Ohio, and the Case Management Orders and Rulings entered to date.

GENERAL OBJECTIONS

1. Walgreens objects to providing these responses because they exceed the number of discovery requests Plaintiffs were permitted to serve on the pharmacy defendants under the Court's Case Management Order No. 1.

2. Walgreens objects to providing these responses because Plaintiffs have repeatedly explained that these discovery requests were never intended to be "additional written discovery that requires a response," but instead were meant to "tailor" their prior discovery requests, to which Walgreens has already responded.

3. Walgreens objects to providing these responses because the Special Master directed the parties on July 30, 2018 that "defendants should read Plaintiffs 'additional requests'

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WAGMDL00101703; WAGMDL00108983; WAGMDL00128847; WAGMDL00129432;
WAGMDL00245867; WAGMDL00289026; WAGMDL00289031; WAGMDL00289436;
WAGMDL00289440; WAGMDL00289045; WAGMDL00289450; WAGMDL00289054;
WAGMDL00303383; WAGMDL00308327; WAGMDL00311411; WAGMDL00325172;
WAGMDL00325187; WAGMDL00371292; WAGMDL00387635; WAGMDL00387641;
WAGMDL00387642; WAGMDL00387651; WAGMDL00400357; WAGMDL00400358;
WAGMDL00400359; WAGMDL00400360; WAGMDL00400361; WAGMDL00400365;
WAGMDL00528179; WAGMDL00589682; WAGMDL00589684; WAGMDL00624527;
WAGMDL00657563; WAGMDL00659828; WAGMDL00660331; WAGMDL00667936;
WAGMDL00667938.

REQUEST NO. 3:

Please identify and describe each *suspicious order* your Suspicious Order Monitoring System (SOMS) identified since January 1; 2006 and produce all documents related thereto; please identify the Bates stamp range for each related to *Case Track One*.

RESPONSE:

Walgreens incorporates its general objections above, including without limitation that this constitutes an improper discovery request beyond the number allowed under CMO 1. Walgreens objects to this request because it provides no definition of “Suspicious Order Monitoring System (SOMS).” Walgreens further objects to this request to the extent it requires Walgreens to “describe” suspicious orders. Walgreens’ produced documents speak for themselves. Walgreens further objects to this request to the extent it requires Walgreens to identify and describe “each” suspicious order identified under the undefined Suspicious Order Monitoring Systems policies. Walgreens will identify certain representative documents that it has been able to locate after a reasonable search. Walgreens may rely on additional documents

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contained it in its production to reflect the suspicious orders Walgreens identified regarding prescription opioids in the Track One jurisdiction for the relevant time frame.

Subject to and without waiving these objections, Walgreens responds that it has produced over 5,000 Suspicious Control Drug Orders (i.e. Suspicious Order Reports) for the Track One jurisdictions. *See* WAGMDL00390035-WAGMDL00395922; WAGMDL00396034-WAGMDL00400341. Walgreens further responds that additional Suspicious Order Reports can be found in its custodial files. Walgreens will supplement this response with additional information as required.

SECOND SUPPLEMENTAL RESPONSE:

Walgreens incorporates by reference its objections and response to this Request as set forth above. Walgreens further objects to this Request because it does not, in fact, seek a description of the operation and evolution of Walgreens' suspicious order monitoring program, even though Plaintiffs represented to Judge Polster on November 20, 2018, that it did, in a hearing that was not on the record. Walgreens has produced a significant volume of information regarding its policies and procedures for suspicious order monitoring, and how those policies and procedures have evolved over time in response to changing guidance from DEA. *See supra*, Response to Request No. 2, including Supplemental Responses. That information includes not just documentary evidence of Walgreens' SOMS policies and procedures, but also 30(b)(6) testimony from Walgreens' corporate designee, Ed Bratton, on December 16, 2018, as well as testimony from other witnesses knowledgeable about Walgreens' SOMS policies over time.

Subject to and without waiving these objections, Walgreens supplements its response to Request No. 3 as follows:

Walgreens has always complied with relevant statutes, regulations, and its best understanding of DEA guidance regarding the identification and reporting of potentially

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suspicious orders. Walgreens’ methodology for reporting potentially suspicious orders to DEA has evolved over time to reflect DEA’s changing guidance and Walgreens’ changing understanding of DEA’s expectations. Walgreens has always worked to strike the right balance between (a) providing patients with FDA-approved medications pursuant to prescriptions written for a legitimate medical purpose and (b) preventing suspicious orders from being filled and shipped to Walgreens pharmacies.

During the period when Walgreens distributed opioids to its pharmacies, federal regulations required Walgreens to report “suspicious orders” to the DEA, meaning “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 CFR § 1301.74(b). As DEA acknowledged to Walgreens in 2007, “the controlled substance suspicious order regulation does not provide detailed, specific guidance...” WAGMDL00387635.

In 2006, the Detroit DEA Field Office admonished Walgreens for not basing its reporting of potentially suspicious orders on the “voluntary formula” found in Appendix E-3 of the Chemical Handler’s Manual. *See, e.g.*, WAGMDL00709507, at 9510; WAGMDL00387635, at 7636; WAGMDL00395965, at 6010. Thereafter, Walgreens pursued the necessary programming to modify its reporting in accordance with the formula described in Appendix E-3. *See, e.g.*, WAGMDL00387642; WAGMDL00400357. Between 2006 and 2008, Walgreens repeatedly informed DEA that its reporting of potentially suspicious orders was based on this guidance, which was also available on DEA’s website. *See* WAGMDL00387642; WAGMDL00387635, at 7636; WAGMDL00387651; *see also* WAGMDL00395965; WAGMDL00400361.

The DEA’s Appendix E-3 formula calculates the quantity which, if exceeded in one month, constitutes an order which “**may** be considered excessive or suspicious and therefore

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require reporting to DEA.” WAGMDL00395965, at WAGMDL00396010 (emphasis in original); *see also* WAGMDL00400361, at WAGMDL00400363 (emphasis in original). The DEA formula is based on a DEA factor, multiplied by an average order for customers of a given distribution center. *See id.* at WAGMDL00400364. The DEA factor “equals 3” for both Schedule II controlled substances, and Schedule III controlled substances containing List 1 chemicals. *Id.* DEA’s guidance instructs distributors to transmit reports based on this formula “[a]t the end of each month.” *Id.* DEA described this formula as intended to apply to “all aspects of commercial chemical manufacturing and distribution.” *Id.* at WAGMDL00400361. DEA explained, “Using a computer to manage and report on high volume transaction business activities with extremely short order cycle times (receipt to delivery) is the only viable, cost effective methodology for the reporting of orders which may be considered excessive or suspicious.” *Id.* at WAGMDL00400364.

Based on DEA’s guidance, Walgreens reported potentially suspicious orders—i.e., orders that “**may** be considered excessive or suspicious”—to the DEA (Suspicious Control Drug Order reports) using this DEA formula until 2012. *See* WAGMDL00387635; WAGMDL00387642; WAGMDL00387651; WAGMDL00400357. Walgreens has also provided Rule 30(b)(6) testimony describing these reports to the DEA of potentially suspicious orders. *See* 12/16/18 Bratton 30(b)(6) Tr. 60:21-63:10; *see also generally id.*

In addition, Walgreens used “line limits” to identify and stop potentially suspicious orders at various points in time. The line limit was a hard stop for certain products that could not be exceeded. *See* 12/16/18 Bratton 30(b)(6) Tr. 191:24-193:10; *see also, e.g.,* WAGMDL00077016; WAGMDL00659828 at WAGMDL00659845.

Starting in 2008, Walgreens began development of a new suspicious order monitoring system (SOMS) that, ultimately, led to a new method of reporting suspicious orders to the DEA.

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Beginning in 2009, Walgreens’ new SOMS identified flagged orders of controlled substances based on algorithms for “tolerance” (i.e., limits on the size of an individual store order for an individual drug) and “frequency” (limits on the frequency with which a particular product could be ordered). *See* WAGMDL00624527; WAGMDL00492132; WAGMDL00667938; WAGMDL00658782; *see also generally* Supplemental Response to Request No. 2, *supra*. Phase I of this new system was launched in August 2009. *See* WAGMDL00667938, at WAGMDL00667940. Starting in Phase II, which launched in September 2010, Walgreens’ suspicious order monitoring system automatically reduced orders that exceeded the SOMS tolerance threshold. *See id.* Phases III and IV entailed enhancements to the system that rolled out in 2012. *See id.*

In late 2012, Walgreens replaced the frequency algorithm with an algorithm that flags orders based on “ceiling limits” (i.e., limits on the overall quantity of an individual drug that a single store could purchase over a specified time period). *See* WAGMDL00667938; WAGMDL00658782; WAGMDL00007981; *see also generally* Supplemental Response to Request No. 2, *supra*.

Also in 2012, Walgreens changed its method of reporting suspicious orders to the DEA, based on its enhanced SOMS, as well as changes in DEA guidance and industry practice. Walgreens performed diligence on orders that flagged on a tolerance or ceiling limit and reported to the DEA any such flagged orders that could not be justified based on the store’s legitimate needs and were therefore deemed to be suspicious. Walgreens has also provided 30(b)(6) testimony on these changes in Walgreens’ methods of identifying potentially suspicious orders and reporting suspicious orders. *See* 12/16/18 Bratton 30(b)(6) Tr. 62:9-20; 149:22-150:17; 151:17-152:7; 227:1-13.

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Walgreens reported suspicious orders to the DEA using this SOMS methodology until Walgreens stopped distributing controlled substances to its pharmacies. Walgreens conducted a diligent search but did not identify any reports to the DEA of suspicious orders of opioids, using this SOMS methodology, from Walgreens stores in the Track One jurisdictions.

REQUEST NO. 4:

Please identify each suspicious order you *reported* to the DEA since January 1, 1996 and produce all documents related thereto; please identify the Bates stamp range for each related to *Case Track One*.

RESPONSE:

Walgreens incorporates its general objections above, including without limitation that this constitutes an improper discovery request beyond the number allowed under CMO 1. Walgreens objects to this request because it provides no definition of “suspicious order.” Walgreens further objects to this request to the extent it requires Walgreens to identify “each” suspicious order reported to the DEA over more than two decades, and is therefore overly broad, unduly burdensome, and well outside the bounds of the Federal Rules’ requirement that discovery be proportional to the needs of the case. Walgreens will identify documents that it has been able to locate after a reasonable search. Walgreens may rely on additional documents contained in its production to reflect the suspicious orders Walgreens identified regarding prescription opioids in the Track One jurisdiction for the relevant time frame.

Subject to and without waiving these objections, Walgreens incorporates by reference its response to Request No. 3 and will supplement this response with additional information as required.

SUPPLEMENTAL RESPONSE:

Walgreens incorporates by reference its objections and response to this Request as set forth above. Subject to and without waiving these objections, Walgreens supplements that

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Dated: February 19, 2019

Respectfully submitted,

WALGREEN CO. AND WALGREEN EASTERN
CO.

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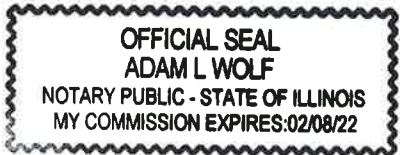
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VERIFICATION

I, Edward Bratton, subject to the penalties and laws relating to unsworn falsification to authorities, including 28 U.S.C. § 1746, state as follows:

I am a manager in the Pharmaceutical Integrity department at Walgreen Co., and am authorized to make this verification on behalf of Walgreen Co. and Walgreen Eastern Co. (“Walgreens”). I am making this verification on behalf of Walgreens only and no other party. The information provided by Walgreens in these Second Supplemental Responses to Plaintiffs’ “(First) Combined Discovery Requests” has been compiled by employees and legal counsel for Walgreens. Although I do not have personal knowledge of all of the information set forth herein, I am informed and believe that the matters stated herein are true and correct.

Dated: March 5, 2019




Edward Bratton, Manager,
Pharmaceutical Integrity, on behalf of
Walgreen Co. and Walgreen Eastern Co.


Adam Wolf 3/5/19